MINOR SPECIES ANIMAL HEALTH COALITION

September 8, 1997

97N-0217

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
Food & Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Docket 97N-0217
Request for Comments on Development of Options to Encourage Animal Drug Approvals for Minor Species and for Minor Uses

Dear Dr. Sundlof:

The undersigned organizations are part of the Minor Species Animal Health Coalition whose mission is to develop and help implement transitional and long-term solutions to allow the safe use of animal drugs in feed for minor species in a manner acceptable to both industry and CVM. The Coalition is pleased to submit the attached "concept paper" which provides for increasing animal drugs to minor species via the recently-approved Veterinary Feed Directive (VFD). This letter and concept paper have also been filed with the FDA Dockets Management Branch as the comments for the Coalition. Individual organizations may also make separate comments on behalf of their respective organizations.

The Coalition believes the VFD approach offers the best opportunity to safely provide animal drugs in feeds to minor species and maintain public and animal health. This approach follows CVM's stated goal of delivering more and safer drugs to animal producers. As provided for in the VFD program, the oversight by the veterinary medical profession would add another layer of protection in the safe delivery of animal drugs to producers. The attached plan allows only for use of therapeutic and prophylactic animal drugs sanctioned by CVM in a VFD manner for minor species only.

After reviewing the concept paper, we hope to schedule a meeting with you and your staff with several representatives of the Coalition to review the ideas presented here and answer any questions. At a later date, the Coalition would appreciate the opportunity to hold a half-day symposium with Coalition members presenting an overview of their industries and how the plan might be implemented. An updated concept presentation could be made at that time as well.

Thank you for your continued interest in securing additional, safe animal drugs for minor species production.

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If you have any questions, please contact the Coalition coordinator, Richard Sellers at the American Feed Industry Association offices (703/524-0810).

Sincerely,

American Feed Industry Association
American Ostrich Association
American Veterinary Medical Association
American Sheep Industry Association
National Aquaculture Association
North American Gamebird Association

cc: FDA Docket 97N-0217

MINOR SPECIES ANIMAL HEALTH COALITION

CONCEPT PAPER -- MEDICATED FEED USE OF APPROVED ANIMAL DRUGS IN UNAPPROVED MINOR SPECIES

A. INTRODUCTION AND BACKGROUND

The mission of the Minor Species Animal Health Coalition is to develop and help implement transitional and long-term solutions to allow the safe use of animal drugs in feed for minor species in a manner acceptable to both industry and CVM.

Minor species animal producers need therapeutic and prophylactic animal drugs for treating a variety of diseases and conditions for which there are no FDA-approved drugs for the specific minor species in question. In keeping with modern animal husbandry practices, these drugs can be efficiently administered via medicated feed. In some cases (e.g., aquaculture), there are no practical alternatives to feed administration.

Ideally, there would be FDA-approved drugs for these uses. As a practical matter, however, drug sponsors do not have sufficient economic incentives to pursue drug approvals for these limited markets. This situation is exacerbated by today's relatively stringent approval requirements for animal drugs for minor species.

Feed manufacturers can produce medicated feeds and premixes for these minor species uses, but need assurances that such feed manufacturing and distribution are not likely to result in either FDA regulatory action or increased product liability exposure.

Having reasonable medical and scientific justifications for the intended minor species uses and use levels in question benefits all persons involved in the use, decision to use, and manufacture of the medicated feed. For animal owners, such justification increases the likelihood of receiving an economic benefit from the drug use. For veterinarians and feed manufacturers, it reduces the likelihood of litigation based on malpractice and product liability theories, respectively.

Under long-standing provisions of the Federal Food, Drug, and Cosmetic Act (FDC Act), any use of an FDA-approved new animal drug, including a drug used in medicated feed, in a manner inconsistent with its FDA-approved labeling was unlawful.

FDA has a long history of addressing, as a matter of enforcement discretion, the use in food animals of animal drugs in a manner inconsistent with their FDA-approved labeling. FDA adopted its first Compliance Policy Guide (CPG) on "extra-label use" of animal drugs in 1984. In addition to establishing the agency's highest priorities for regulatory attention (e.g., certain listed drugs of particular human food safety concern), the CPG set forth the general conditions under which the use of an animal drug in a manner inconsistent with its approved labeling would not ordinarily be the subject of regulatory action, including the following:

- The drug use decision is made by an attending veterinarian within the context of a valid veterinarian-client-patient relationship;

- There is no approved drug for the species and intended use in question;
- The identity of the treated animals is maintained;
- Extended withdrawal periods are assigned and followed to prevent illegal drug residues; and
- The drug bears labeling information which is adequate to assure safe and proper use.

With enactment of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), Congress authorized FDA to establish, by regulation, the conditions for the lawful use of animal drugs in a manner inconsistent with their FDA-approved labeling. FDA's implementing regulations have, for the most part, codified the provisions of the "extra-label use" CPG.

Drugs used in medicated feed, however, are expressly beyond the scope of AMDUCA. Therefore, the use of approved animal drugs in medicated feed for unapproved minor species should be addressed by FDA by means of a CPG, much as FDA addressed "extra-label use" in a CPG before the enactment of AMDUCA.

One federal court dismissed a challenge to the "extra-label use" CPG by veterinarians on the bases that there were no issues appropriate for judicial review, and that the plaintiffs could only raise general grievances that were most appropriately addressed by Congress. Cowdin v. Young, 681 F.Supp. 366 (W.D. La. 1987). The Cowdin court's reasoning should be equally applicable if a new CPG addressing the use of approved medicated feed drugs in unapproved minor species should be challenged.

The "extra-label use" CPG stated that the "extra-label use" of drugs in medicated feed was an enforcement priority. This position, as well as the fact that AMDUCA excluded medicated feed drugs, stemmed from the feed industry's longstanding view that mixing medicated feed pursuant to a veterinarian's "prescription" would have resulted in medicated feed being regulated as a "prescription" drug under state pharmacy laws. These pharmacy requirements, which were intended for dosage form drug products and not medicated feed, would have represented a major disruption of existing production and marketplace practices for feed producers and distributors.

For example, feed mills would have had to employ a registered pharmacist to oversee all feed mixing operations; they also would have had to comply with retail pharmacy requirements (e.g., pharmacy counter).

The Animal Drug Availability Act of 1996 (ADAA) created the "veterinary feed directive" (VFD) category of animal drugs to provide an alternative to "prescription" status for certain medicated feed drugs. Like a "prescription" drug, a VFD drug can only be used when called for by a licensed veterinarian within the context of a valid veterinarian-client-patient relationship. Importantly, however, by federal law a VFD drug or feed is not a "prescription" article under state law. Thus, state pharmacy requirements have no applicability to VFD drugs and feeds, and

the practical problems associated with "prescription" medicated feeds do not exist with VFD drugs and feeds.

The availability of the VFD mechanism presents an opportunity for FDA and industry to address the need for medicated feed drugs for minor species.

Another reason for the feed industry's long-standing opposition to "extra-label" drug use in medicated feed was concern about human food safety and the potential for regulatory and financial liability in the event of unlawful drug residues in food of animal origin. These concerns are lessened significantly if there is some FDA involvement -- even on an informal level that falls short of the procedure used to approve animal drugs -- in determining the drugs that can be used in unapproved minor species and the associated conditions of use (e.g., use levels, withdrawal times).

B. SCENARIO FOR USE OF APPROVED ANIMAL DRUGS IN UNAPPROVED MINOR SPECIES

By CPG, FDA would state that, as a matter of enforcement discretion, the use of certain specific approved therapeutic and prophylactic animal drugs administered in medicated feed for unapproved minor species is not a matter of regulatory concern. In contrast with the prior CPG (which only listed a few drugs that were regarded as enforcement priorities), the CPG would list specific drugs, minor species uses, use levels, withdrawal times, and other relevant details that ordinarily would not be of regulatory concern.

CVM's decision to list specific drugs and conditions of use in the CPG would be based on its review of one or more of the following:

- Drug monographs prepared by the U.S. Pharmacopoeial Convention.
- Extrapolation of drug approval data (e.g., from chickens to pheasants).
- Published literature.
- Unpublished data and information submitted to CVM by producer organizations, veterinarian associations, drug sponsors, academicians, or others.

The type and extent of data and information needed to support CVM recognition of a minor species drug use should be realistic. If the standard for CVM recognition is too stringent, the VFD-CPG concept will be of no practical utility.

To get the benefit of FDA's enforcement discretion (to not take regulatory action) under the CPG, drug usage would have to be pursuant to a valid VFD, issued in the context of a valid veterinarian-client-patient relationship. The conditions of use set forth in the CPG would have to

be followed. Relevant provisions of FDA's VFD implementing regulations, when adopted, would be applicable (e.g., recordkeeping and inspection, one-time distributor notification, written acknowledgment of distribution limitations).

The CPG could be crafted in a fashion similar to the "extra-label use" CPG. Use of the VFD process would establish procedures and safeguards comparable to the general conditions for "extra-label use" set forth in the former CPG.

The ADAA requires FDA to announce, by April 1998, its legislative and regulatory proposals for facilitating minor species approvals. Hopefully, within a few years, these reforms will make it economically feasible for drug sponsors to seek minor species approvals. The minor species CPG discussed in this Concept Paper is needed to fill an urgent current need. At the same time, the CPG should not remove incentives for drug sponsors to seek approvals for minor species after FDA's reform measures go into effect. To address both concerns, the CPG could be viewed as an interim measure and include a general "sunset" provision. It could also provide that, after the general "sunset" date and absent extenuating circumstances, no newly developed drug and minor species use would be listed in the CPG for longer than a specified number of years. This approach assumes that the sponsor of a newly developed animal drug is unlikely to pursue a minor species approval until after the drug has been approved and marketed for a major species.